UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,314	05/17/2005	David Wallach	WALLACH33	6672

1444 7590 04/20/2009

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
04/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,314	WALLACH ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,25,69,70,72,75,82-91,100 and 102-105* is/are pending in the application.

4a) Of the above claim(s) *20,25,72,84 and 89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69,70,75,82,83,85-88,90,91 and 102-105* is/are rejected.

7)☒ Claim(s) *69,70,75,82,83,85-88,90,91 and 102-105* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0309*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' filing of March 24, 2009, in response to the action mailed September 25, 2008, is acknowledged. It is acknowledged that applicants have cancelled Claims 21-24, 66-68, 73-74, 76-81, and 101, amended Claims 20, 25, 69, 70, 72, 75, 82-91, and 100, and added Claim 102-105. Claims 20, 25, 69, 70, 72, 75, 82-91, 100, and 102-105 are pending. The elected invention is directed to a method for treatment of rheumatoid arthritis, a disease involving IL-2, using the NIK polypeptide of SEQ ID NO: 18. Claims 20, 25, 72, 84, and 89 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 69, 70, 75, 82, 83, 85-88, 90, 91, and 102-105 are hereby considered.

It is noted that Applicants' remarks, filed March 24, 2009, have many typographical errors; for example, pg 10, parg 3, pg 11, parg 6, pg 12, pargs 1, 3, and 5 etc. The Examiner has done her best to reply to Applicants' remarks.

Claims-Objections

Claims 69, 70, 75, 82, 83, 85-88, 90, 91, and 102-105 are object to for reciting non-elected subject matter, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 69, 70, 75, 82, 83, 85-88, 90, and 91 under 35 U.S.C. 112, first paragraph/lack of enablement, for the reasons explained in the prior action, is maintained.

Claims 102-105 are herein rejected under 35 U.S.C. 112, first paragraph/lack of enablement, for

the same reasons. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) As it has been shown in the present specification, the polypeptides used in the present method interfere with NIK/cyc interaction. The type of disease that can be treated in accordance with the present invention is adequately defined in claim 69.

(B) The specification discloses that activation of the NF-KB pathway is involved in the pathogenesis of many specified diseases (pg 5, line 16, through pg 7, line 15). The specification establishes that cyc and NIK interaction induces NF-KB activation and that inhibition of cyc/NIK interaction inhibits NIK mediated NF-KB activation (pg 20, line 9 to pg 21, line 4; all Examples). Thus, all of those diseases mediated by NF-KB are necessarily diseases in which NIK and cyc interaction is involved in the pathogenesis of the disease.

(C) The specification [pg 6], line 16, through page 7, line 15, is specifically directed to diseases in which NF-KB activation is involved.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: It is acknowledged that specification teaches that the C-terminal fragment of a NIK1, consisting of SEQ ID NO: 18, binds a cyc in the yeast two-hybrid system and that a NIK1 and a cyc are co-immunoprecipitated from cells over-expressing these proteins (Example 1-2). However, the specification also teaches that it is questionable as to whether the peptide of SEQ ID NO: 18 binds to a full-length cyc protein (Table 1). The examiner also fails to see where the specification teaches that the peptide of SEQ ID NO: 18 interferes with NIK/cyc interaction.

The specification also fails to provide evidence that the peptide of SEQ ID NO: 18, or any derivative thereof, will bind to any protein, having any structure, and having the activity of a cyc protein. Determining which proteins, having any structure, and having the activity of a cyc protein, that the peptide of SEQ ID NO: 18, or derivative thereof, will bind represents undue experimentation.

It is acknowledged that Claim 69 recites treatment of any disease in which NIK/cyc interaction is involved. However, the specification fails to disclose the specific diseases encompassed and determining which specific diseases are encompassed represents an undue burden on the skilled artisan.

(B) Reply: It is acknowledged that specification establishes, in a recombinant reporter system, that cyc and NIK interaction induces NF-KB activation and that the C-terminal fragment of a NIK1, consisting of SEQ ID NO: 18, inhibits NIK-induced activation of NF-kB transcription (pg 20, parg 3). However, the specification does not provide evidence that inhibition of cyc/NIK interaction inhibits NIK mediated NF-KB activation. The specification also fails to provide evidence that all diseases mediated by NF-KB, or any specific disease mediated by NF-KB, are necessarily diseases in which NIK and cyc interaction is involved. As acknowledged by Applicants, interaction of the C-terminal region of NIK binds with NIK's N-terminal region, inactivates the kinase, and competes with binding of the kinase to it's substrates [0158]. Thus, the effect of SEQ ID NO: 18 on NIK may be a direct effect, independent of cyc.

(C) Reply: It is acknowledged that specification teaches that NF-kB may be involved in the inflammatory diseases inflammatory bowel diseases, atherosclerosis, and Alzheimer's

disease. However, the specification does not teach that NIK and cyc interaction is involved in inflammatory bowel diseases, atherosclerosis, and Alzheimer's disease.

Even if the specification taught that the peptide of SEQ ID NO: 18 was effective at treating one specific disease wherein the interaction of NIH/cyc played a role, which the specification does not teach, determining which diseases, wherein the interaction of any protein, having any structure and having the activity of NIH, with any protein, having any structure and having the activity of cyc, played a role, can be effectively treated with the peptide of SEQ ID NO: 18 represents undue experimentation.

For these reasons and those explained in the prior actions, Claims 66, 67, 69, 70, 73-78, 80-83, 85-88, 90-93, 95-98, 100, and 101 are rejected under 35 U.S.C. 112, first paragraph/lack of enablement.

Written Description

Rejection of Claims 69, 70, 75, 82, 83, 85-88, 90, and 91 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior action, is maintained. Claims 102-105 are herein rejected under 35 U.S.C. 112, first paragraph/ written description, for the same reasons. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. It appears that the only objection that the examiner now has relates to [functional derivatives?]

This argument is not found to be persuasive for the following reasons. It is Applicants who presented the issue of functional derivatives in their prior response. The Office was merely responding to Applicants' prior argument.

As explained in the action of April 11, 2007, the specification fails to describe a method for treating any disease using any variant of a NIK protein in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Regarding the instant claims, they are directed to a genus of methods for treating any disease using the peptide of SEQ ID NO: 18, where the interaction of any NIK protein and any cyc protein plays a role in the disease. The specification teaches no such methods. Thus, the specification fails to describe said genus of methods in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652